

CATALYST IMPLEMENTATION BRIEF

Designing an innovative contract

Once the decision has been made to move forward with an innovative contract for a specific medical treatment, the details of a contract must be designed. This brief offers a checklist of the key elements that developers, payers, and any other stakeholders should consider during the contract design and negotiation process.

What's covered

- Contract scope and eligibility
- Outcomes-based or risk-based contracts
- Third party roles and responsibilities
- Contract governance
- Potential contract exclusions
- Sources

CONTRACT SCOPE AND ELIGIBILITY

First, determine the group of patients who will be covered by the contract and other aspects of the contract's scope. Eligible utilization is typically based on agreed-upon medical guidelines or prior authorization requirements drawn from a product's FDA label and clinical trials.

- Contract period
- Eligible patients based on plan enrollment, including consideration of plan type
- Product under contract
- Type of contract
- Eligible utilization
- Medical guidelines or prior authorization inclusion and exclusion criteria
- Formulary placement/status relative to competitive products
- Required site of care, such as a qualified treatment center or Center of Excellence
- Timing of product payment

OUTCOMES-BASED OR RISK-BASED CONTRACTS

Many innovative contracts are **outcomes-based contracts**, which link payment for a treatment with real-world outcomes representing whether the treatment meets performance expectations for a patient or population. Another common contract type is **risk-based contracts**, which link payment to a distribution of risk for the product's performance to fail, assuming that performance will vary for different patients. A **warranty contract** is typically an outcomes-based contract that is outsourced to a third-party.

For these contracts, the following elements will need to be assessed.

- Identification of performance-based outcome or risk-based measurement

- Identification of data source, i.e. claims, EHR, PRO
- Treatment date(s)
- Patient measurement period
- Identification of measurement timing relative to treatment
- Definition of performance success or failure (missed outcome or adverse event/rebate criteria)
- Reporting timing
- Calculation of outcome-based or risk-based payment
- Payment timing
- Data use and privacy protection

Other contract types will require different elements. See the [NEWDIGS Paying for Cures Toolkit](#) for more details about other types of contracts, including [payment over time](#), [subscription models](#), [reinsurance or stop loss insurance](#), and [risk pools](#).

THIRD PARTY ROLES AND RESPONSIBILITIES

In addition to developers and payers, third-party service providers may be involved in implementing innovative contracts. These providers may be particularly useful for organizations that are smaller or have fewer resources to devote to aspects of implementation such as collecting and analyzing outcomes data.

- Identify potential third parties to support contract management.
- Clarify roles and responsibilities.
- Map out communication and data flows and timing.
- For warranty contracts, a third party will identify the payer premium based on the third party's underwriting.
- The third party will be responsible for implementation and execution of the contract.

- The developer will use the premium to calculate Medicaid Best Price.
- Developers will want to incorporate payer requirements into the warranty contract requirements.

CONTRACT GOVERNANCE

Incorporating governance elements into an innovative contract is an important step to prepare for the possibility of any disputes in the future. These elements are common across different types of contracts.

- Map out communication and data flows, including with third parties
- Remedy of reporting errors
- Time period for notification of error
- Management of disputes
- Audit rights
- Payment disputes
- Contract termination and/or renewal terms
- Record retention

POTENTIAL CONTRACT EXCLUSIONS

There may be some situations that warrant an exclusion from eligibility or limitation in pay out. It's important to consider potential exclusions during the contract design process. Examples include:

- 340B Contract pharmacies
- Cap on payments not to exceed Medicaid Best Price
- Other specific patient populations exclusions aligned to clinical trials or the product label

SOURCES

[Implementation Brief: Innovative contracting 101](#)

[Implementation Brief: Key terms for payment innovation](#)

[Implementation Brief: Is an innovative contract right for you?](#)

[Paying for Cures Toolkit: Precision Financing Solutions](#)

[Lyfegen](#) contracts database